



MLKC CONSULTING, LLC

Life Science Quality and Regulatory Experts

GMP & FDA Compliance Training Checklist

This checklist outlines best practices for training employees on FDA compliance and Good Manufacturing Practices (GMPs). Proper training ensures regulatory adherence, reduces compliance risks, and improves operational efficiency.

Use this checklist to:

- Develop structured GMP training programs
- Ensure job-specific training for employees
- Maintain documented training records for FDA audits
- Conduct refresher training and compliance updates
- Prepare employees for FDA inspections and compliance expectations

1. Develop a Structured Training Program

- Define GMP training requirements for all job roles.
- Ensure new employees complete compliance training before starting work.
- Provide training on FDA regulations, data integrity, and documentation best practices.

2. Implement New Employee GMP Training

- Ensure new hires receive GMP and compliance training before performing job duties.
- Cover FDA regulations, company policies, and cleanroom procedures.
- Conduct assessments or quizzes to confirm employee understanding.

3. Provide Job-Specific Training

- Train employees on specific tasks that impact compliance (e.g., batch records, cleanroom operations, CAPA).
- Use hands-on training, demonstrations, and shadowing programs.
- Ensure employees understand their role in maintaining compliance.

4. Train Employees on Good Documentation Practices (GDPs)

- Ensure employees follow ALCOA+ principles (Attributable, Legible, Contemporaneous, Original,

Accurate, Complete, Consistent, Enduring, Available).

- Train employees on how to properly complete batch records and logbooks.
- Conduct refresher training on documentation best practices.

5. Prepare Employees for FDA Inspections

- Train employees on how to respond to FDA inspector questions.
- Conduct mock FDA audits to test employee preparedness.
- Ensure employees understand the importance of compliance and data integrity.

6. Maintain Training Records & Documentation

- Track training dates, topics, trainers, and employee assessments.
- Use an electronic training management system (eTMS) to monitor compliance.
- Ensure records are easily accessible for FDA audits.

7. Conduct Ongoing Refresher Training

- Schedule annual GMP training sessions for all employees.
- Provide updates on new FDA regulations and compliance trends.
- Incorporate lessons learned from internal audits and regulatory inspections.

Pro Tip: Strengthening Employee Compliance Training

- * Ensure training is interactive and includes real-world case studies.
- * Conduct periodic knowledge checks to confirm employee understanding.
- * Maintain up-to-date training records to demonstrate compliance during FDA audits.
- * Foster a culture of quality by encouraging employees to report compliance concerns.

Need Expert Support for GMP & Compliance Training?

MLKC Consulting, LLC specializes in FDA compliance training, GMP program development, and employee readiness for regulatory audits. Contact us for expert guidance!

Contact us today for a Consultation!

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